

UNITED STATE PARTMENT OF COMMERCE Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

AUG - 3 1999

Margaret Brumm
Eli Lilly and Company
Patent Division/MMB
Lilly Corporate Center
Indianapolis, IN 46285

Re:

Patent Term Extension

Application for U.S. Patent No. 4,808,614

#22

Dear Ms. Brumm:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,808,614 for a period of 1,537 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

cc: David T. Read

Acting Director Regulatory Policy Staff, CDER

Food and Drug Administration 1451 Rockville Pike, HFD-7

Rockville, MD 20852

Re: GEMZAR® (gimcitabine) FDA Docket No. 96E-0314

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

PATENT NO.

4,808,614

ISSUED

February 28, 1989

INVENTOR(S)

Larry W. Hertel

PATENT OWNER

Eli Lilly and Company

PRODUCT

GEMZAR® (gimcitabine)

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,537 days

from February 28, 2006, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

AMPERICA STATE OF THE PRICE STAT

I have caused the seal of the Patent and Trademark Office to be affixed this 27th day of July 1999.

Q. Todd Dickinson

Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks